

## **REMARKS**

Claims 1-3, 6-10, and 14-19, and 25-28 are pending in the application.

By the foregoing Amendment, claims 1 and 15 are amended, and claims 13 and 24 are canceled without prejudice or disclaimer.

Claims 1 and 15 are amended to incorporate the limitations of canceled claim 13.

These changes are believed not to introduce new matter, and entry of the Amendment is respectfully requested.

Based on the above Amendment and the following Remarks, Applicant respectfully requests that the Examiner reconsider all outstanding rejections, and withdraw them.

### **Rejections under 35 U.S.C. § 112, ¶ 2**

On page 2 of the Office Action, claims 1-3, 6-10, 13-19, and 24-28 were rejected under section 112, second paragraph, as being indefinite due to the recitation in claims 1 and 15 of “a planar test surface having a specific affinity.” This rejection is believed to be overcome by the amendment of claims 1 and 15 and the cancellation of claims 13 and 24. Specifically, claims 1 and 15 are amended to recite “a ferroelectric transducer having a planar test surface comprising a coating of probe molecules.” The coating of probe molecules have a specific affinity to an analyte for selectively capturing or binding the analyte in said sample. Support of the amendments may be found at page 4, paragraph [0021] of the description as originally filed.

Rejections under 35 U.S.C. § 103

*1. Claims 1-3, 6-13, 15-19, and 21-24*

On page 4 of the Office Action, claims 1-3, 6-10, 13, 15-19, 24, 27, and 28 were rejected under section 103(a) as being unpatentable over U.S. Pat. No. 5,866,321 to Matsue et al. (“Matsue”) in view of U.S. Pat. No. 7,163,659 to Stasiak et al. (“Stasiak”), and further in view of U.S. Pat. No. 5,922,537 to Ewart et al. (“Ewart”). To the extent the Examiner may consider this rejection to be applicable to claims 1 and 15 as amended to incorporate the limitations of claim 13, it is respectfully traversed.

The Office Action acknowledges that U.S. Pat. No. 5,866,321 (“Matsue”) does not teach “a ferroelectric transducer” as recited in claims 1 and 15. It therefore also follows that Matsue does not teach “immobilizing said analyte in said sample on a ferroelectric transducer” as recited in claims 1 and 15.

In fact, Matsue does not suggest or teach use of ferroelectric materials as the substrate for the sample. On the contrary, Matsue teaches away from the invention at column 9, lines 57 to 58, by teaching use of a non-ferroelectric substrate, i.e. “an insulating substrate such as a silicon wafer, a glass, or a synthetic resin.” As noted in MPEP 2143, “combining known prior art elements is not sufficient to render the claimed invention obvious if the results would not have been predictable to one of ordinary skill in the art”; and a teaching away is thus highly suggestive of non-predictability and nonobviousness. Still further, as noted in MPEP 2141.02 (citing *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984)), “A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention.”

The Office Action characterizes Ewart as teaching “a method of optimizing a capacitive sensor device by including a dielectric made from ferroelectric ceramic, such as barium titanate”; and asserts that it would have been “obvious to modify Matsue’s method by incorporating Ewart’s barium titanate as a ferroelectric layer.”

Ewart cannot remedy Matsue’s teaching away, because Ewart does not teach “a ferroelectric transducer having a planar test surface comprising a coating of probe molecules” and “establishing an electric field to polarize said analyte in said sample, or sensing an electric response of said ferroelectric transducer resulting from the effect of said electric field in said sample on said ferroelectric transducer, and indicative of the presence of said analyte in said sample,” as required in amended claim 1, or the similar limitations recited in amended claim 15.

In fact, the claimed invention would not result from applying Ewart’s teachings to Matsue because, although Ewart teaches use of ferroelectric materials in the test surface, Ewart teaches away from the invention in that “by removal of such analyte particles from the test surface, the capacitance of the device has changed and hence, a measure of the amount of analyte in the sample can be detected by use for example, of the biosensors of FIGS. 10 and 11.” Column 17, lines 13 to 17.

Stasiak also does not remedy the deficiencies of Matsue, because Stasiak also does not teach “a ferroelectric transducer having a planar test surface comprising a coating of probe molecules” as defined in amended claims 1 and 15. On the contrary, Stasiak teaches away from the invention at column 4, lines 50 to 65 by describing use of non-ferroelectric materials as the substrate. Still further, Stasiak does not teach “a coating of probe molecules having a specific affinity to said analyte, wherein said immobilizing comprises selectively capturing or binding

said analyte to said probe molecules,” as recited in amended claims 1 and 15. Thus the claimed invention also would not result from a combination of Matsue, Ewart, and Stasiak.

Referring to page 4, paragraph [0021] of the description as originally filed, the advantage of the test surface having a coating of probe molecules is that the probe molecules have specific affinity to target analytes. Therefore, the probe molecules will selectively capture or bind the target analytes.

Further, referring to page 8, paragraph [0037] of the description as originally filed, the advantage of having a ferroelectric transducer is to enhance the signal shifts. Specifically, when the biosample contains analytes that are electrically polarized or charged under a potential bias, the biosample becomes electrically polarized. Usually, the higher the concentration of the analyte, the higher the polarization. Thus, the resulting signal shift can be more pronounced when a ferroelectric transducer and biosample are placed adjacent to each other, as compared to using no transducer or a non-ferroelectric transducer. Having a ferroelectric transducer is not a mere matter of design choice, but addresses the problem encountered in sensors, such as for example, optical biosensors, where it is difficult to detect a small volume of sample as described in page 1, paragraph [0005] of the description as originally filed.

In view of the above, a skilled person reading Matsue in combination with Ewart would not be motivated to combine the teachings of Matsue with Ewart to arrive at the invention as defined in amended claims 1 and 15, even with the further teachings of Stasiak. Specifically, Matsue and Ewart teach away from each other in that Matsue does not teach use of a ferroelectric substrate, and the ferroelectric material in Ewart is not configured to sense an electric field in the sample on the ferroelectric material because the sample has to be removed in order to detect the presence of the analyte.

Therefore, it is submitted that a skilled person would require substantial effort and inventiveness to modify the teachings in Matsue by incorporating Ewart's ferroelectric material to obtain the invention as defined in claims 1 and 15. However, the Supreme Court in *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398 (2007) held that if a modification is beyond the skill of a person of ordinary skill in the art, the modification is not obvious. As such, the invention as recited in amended claims 1 and 15 is not obvious in light of Matsue or Ewart singly or in combination.

Adding the teachings of Stasiak does not remedy the defects in the combination of Matsue and Ewart, as neither Matsue nor Stasiak discloses "a ferroelectric transducer" and in the absence of a perceived problem, a skilled person would not find it obvious to modify the teachings in Stasiak and Matsue to arrive at the invention.

As regards to the combination of Stasiak with Ewart, neither Ewart nor Stasiak discloses a problem of difficulty in detecting a small volume of the sample. Therefore, a skilled person would not be motivated to combine Stasiak with Ewart to arrive at the invention. Further, if a skilled person were to combine Stasiak with Ewart, Ewart teaches away from the invention and do not disclose a ferroelectric transducer having a planar test surface comprising a coating of probe molecules" and "establishing an electric field to polarize said analyte in said sample; sensing an electric response of said ferroelectric transducer resulting from the effect of said electric field in said sample on said ferroelectric transducer, and indicative of the presence of said analyte in said sample," as required in amended claim 1. Therefore, a skilled person would require significant effort and inventive skill to modify either Ewart or Stasiak to arrive at the invention, with or without the further teachings of Matsue.

In view of the above, it is submitted that amended claims 1 and 15 are not obvious. By virtue of dependency from amended claims 1 and 15, the dependent claims 2, 3, 6 to 10, 14, 16 to 19, 23, 25 to 28 are not obvious.

*2. Claim 14*

On page 8 of the Office Action, claim 14 was rejected under section 103(a) as being unpatentable over Matsue in view of Stasiak and Ewart, and further in view of U.S. Pat. No. 4,810,639 to Pankratz (“Pankratz”). This rejection is believed to be overcome for the reasons stated above with respect to claim 1, from which claim 14 indirectly depends.

In the Office Action, it was conceded that Matsue, Stasiak, and Ewart “do not teach the step of ‘removing a remaining portion of said sample,’” as recited in claim 14; and Pankratz was cited as supplying this teaching. Pankratz teaches an immunoassay for determining the enzymatic activity of creatine kinase-MB isoenzyme in liquid samples. There is nothing in Pankratz to remedy the deficiencies of Matsue, Stasiak, and Ewart with respect to the method as recited in claim 1. Therefore, Stasiak and Ewart in combination with Pankratz cannot teach or suggest the method as recited in claim 1, much less the method as recited in claim 14.

It is therefore respectfully submitted that the invention as recited in claim 14 is neither anticipated nor rendered obvious by Matsue, Stasiak, and Ewart in combination with Pankratz; and that the rejection should be withdrawn.

*3. Claims 25 and 26*

On page 9 of the Office Action, claims 25 and 26 were rejected under section 103(a) as being unpatentable over Matsue in view of Ewart and Stasiak, and further in view of U.S. Pat. No. 7,527,720 to Ishimaru et al. (“Ishimaru”).

In the Office Action, it was conceded that Matsue, Stasiak, and Ewart a movable electrode as recited in claims 25 and 26; and Ishimaru was cited as supplying this teaching. Ishimaru teaches an electrophoretic device, an electrophoresis apparatus, an electrophoretic method, and a specimen detection method for detecting bio-related substances; and does not include any teaching regarding ferroelectric transducers. There is nothing in Ishimaru to remedy the deficiencies of Matsue, Stasiak, and Ewart with respect to the method as recited in claim 1 or the sensor recited in claim 15. Therefore, Stasiak and Ewart in combination with Ishimaru cannot teach or suggest the method as recited in claim 1 or the sensor as recited in claim 15, much less the method as recited in claim 25 or the sensor recited in claim 26.

It is therefore respectfully submitted that the invention as recited in claims 25 and 26 is neither anticipated nor rendered obvious by Matsue, Stasiak, and Ewart in combination with Ishimaru; and that the rejection should be withdrawn.

### Conclusion

All rejections have been complied with, properly traversed, or rendered moot. Thus, it now appears that the application is in condition for allowance. Should any questions arise, the Examiner is invited to call the undersigned representative so that this case may receive an early Notice of Allowance.

Favorable consideration and allowance are earnestly solicited.

Respectfully submitted,

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**Enclosure: Request for Continued Examination  
Petition for Extension of Time**